A bill to be entitled
An act relating to cardiac programs; amending s. 395.1055, F.S.; requiring the Agency for Health Care Administration to adopt rules establishing licensing standards for pediatric cardiac catheterization and pediatric open-heart surgery programs located in licensed facilities; providing requirements for a facility providing such programs, including requiring the facility to be licensed by the Joint Commission; establishing minimum standards for rules for such pediatric cardiac programs; requiring hospitals with a pediatric cardiac catheterization program to participate in the clinical outcome reporting system operated by the Society of Thoracic Surgeons; requiring the agency to establish a pediatric cardiac technical advisory panel and adopt rules based on the panel's recommendations; providing duties of the panel; specifying membership of the panel; amending s. 408.0361, F.S.; granting an exception from a transfer time protocol requirement for certain hospitals providing adult cardiovascular services; expanding rulemaking criteria for the agency for licensure of hospitals performing percutaneous cardiac intervention procedures; amending s. 408.05, F.S.; requiring the agency to contract with the Society of Thoracic
Surgeons for collection of certain data for publication on the agency's website for certain purposes; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (9) of section 395.1055, Florida Statutes, is renumbered as subsection (11), and new subsections (9) and (10) are added to that section, to read:

395.1055 Rules and enforcement.—

(9)(a) The agency shall adopt rules establishing licensure standards for providers of pediatric cardiac catheterization services and pediatric open-heart surgery.

(b) In establishing licensure standards for a pediatric cardiac catheterization program, the rules, at a minimum, must require:

1. The program to be located in a facility in which pediatric open-heart surgery is being performed and which is completely equipped to provide necessary medical and surgical care to the patient. The facility must be accredited by the Joint Commission.

2. The cardiac catheterization team to include sufficient medical and support staff to provide necessary medical and surgical care to the patient.
3. The program to mobilize the pediatric cardiac catheterization team within a specified period of time for an emergency procedure.

4. The facility where the program is located to offer a range of noninvasive cardiac and diagnostic services, including, but not limited to:
   a. Hematology studies or coagulation studies;
   b. Electrocardiography;
   c. Chest X-rays;
   d. Blood gas studies;
   e. Clinical pathology studies and blood chemistry analysis;
   f. A special procedure X-ray room;
   g. A film storage and darkroom for proper processing of films;
   h. X-ray equipment with cineangiography capabilities;
   i. An image intensifier;
   j. An automatic injector;
   k. A diagnostic X-ray examination table for special procedures;
   l. A blood gas analyzer;
   m. A multichannel polygraph; and
n. Emergency equipment, including a temporary pacemaker unit with catheters, ventilator assistance devices, and a DC-defibrillator.

(c) In establishing licensure standards for a pediatric open-heart surgery program, the rules, at a minimum, must require:

1. The pediatric open-heart surgery team to include sufficient surgical and support staff to provide necessary medical and surgical care to the patient.

2. The program to:

   a. Be available for nonemergent open-heart surgery 8 hours per day, 5 days per week;

   b. Be capable of mobilizing the surgical and medical support teams within a specified period of time for emergency cases; and

   c. Provide 24-hour coverage by a physician or staff.

3. Postoperative care to be provided under the direction of the cardiovascular surgeon who performed the surgery, in communication with and with the support of the postoperative cardiovascular team as prescribed by rule. Members of the team must be on call or otherwise available for an emergency. A patient must be cared for in an intensive care unit that provides 24-hour-per-day nursing care with at least one registered nurse for every two patients during the first hours of postoperative care. Postoperative care must also include
coverage for the operation of the cardiopulmonary bypass pump 24 hours per day.

4. Each pediatric open-heart surgery program to have the capability to provide a full range of open-heart surgery operations, including:
   a. Repair or replacement of a heart valve;
   b. Repair of a congenital heart defect;
   c. Repair or reconstruction of an intrathoracic vessel;
   and
   d. Treatment of cardiac trauma.

5. A licensed facility with a pediatric open-heart surgery program to provide the following services:
   a. Consultation in cardiology, hematology, nephrology, pulmonary medicine, treatment of infectious diseases, and other appropriate pediatric subspecialties;
   b. Pathology, including anatomical, clinical, blood bank, and coagulation laboratory services;
   c. Anesthesiology, including respiratory therapy;
   d. Radiology, including diagnostic nuclear medicine;
   e. Neurology;
   f. Inpatient cardiac catheterization;
   g. Noninvasive cardiographics, including electrocardiography, exercise stress testing, and echocardiography;
   h. Intensive care; and
i. Emergency care available 24 hours per day for cardiac emergencies.

(d) A hospital with a licensed pediatric cardiac catheterization program shall participate in the clinical outcome report system operated by the Society of Thoracic Surgeons.

(10) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric open-heart surgery programs.

(a) Voting members of the panel shall include:

1. A pediatric cardiac surgeon or pediatric cardiologist, or a designee, from each of the following pediatric cardiac centers:
   a. Johns Hopkins All Children's Hospital in St. Petersburg;
   b. Arnold Palmer Hospital for Children in Orlando;
   c. Joe DiMaggio Children's Hospital in Hollywood;
   d. Nicklaus Children's Hospital in Miami;
   e. St. Joseph's Children's Hospital in Tampa;
   f. University of Florida Health Shands Children's Hospital in Gainesville;
   g. University of Miami/Jackson Memorial Medical Center Holtz Children's Hospital in Miami;
   h. Wolfson Children's Hospital in Jacksonville;
i. Florida Hospital for Children, Walt Disney Pavilion, in Orlando; and
j. Nemours Children's Hospital in Orlando.
2. An at-large member, appointed by the Secretary of Health Care Administration, who is either a pediatric cardiologist or adult cardiologist with a special interest in the care of adults with congenital heart disease.

(b) Nonvoting members of the panel shall include:
1. The Secretary of Health Care Administration, or a designee;
2. The Surgeon General, or a designee; and
3. The Deputy Secretary of Children's Medical Services, or a designee.

(c) The Secretary of Health Care Administration may appoint up to four additional nonvoting members from the following organizations:
1. The Florida Association of Children's Hospitals;
2. The Florida Chapter of the American Academy of Pediatrics;
3. The Florida Society of Thoracic and Cardiovascular Surgeons;
4. The Florida Chapter of the American College of Cardiology; or
5. The Florida Chapter of the American Heart Association.
(d) Based on recommendations from the panel, the agency shall develop and adopt rules for pediatric cardiac catheterization programs and pediatric open-heart surgery programs, consistent with the licensure requirements in subsection (9), that include at least the following:

1. Outcome standards specifying expected levels of performance in pediatric cardiac programs, using a risk adjustment procedure that accounts for the variations in severity and case mix. Such standards may include, but are not limited to, in-hospital mortality, infection rates, and returns to surgery.

2. Specific steps to be taken by the agency and a licensed facility when such facility does not meet the outcome standards within specified time periods, including time periods for detailed case reviews and the development and implementation of corrective action plans.

Section 2. Paragraph (b) of subsection (3) of section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.—
(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(b)1. For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or,
for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However,

2. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol requirement in subparagraph 1., if the hospital demonstrates that:

   a. For the most recent 12-month period as reported to the agency, it has provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations, and that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease; or

   b. It has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

3. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have
demonstrated experience in handling acutely ill patients
requiring intervention, based on the staff member's previous
experience in dedicated cardiac interventional laboratories or
surgical centers. If a staff member's previous experience is in
a dedicated cardiac interventional laboratory at a hospital that
does not have an approved adult open-heart-surgery program, the
staff member's previous experience qualifies only if, at the
time the staff member acquired his or her experience, the
dedicated cardiac interventional laboratory:
   a. Had an annual volume of 500 or more percutaneous
cardiac intervention procedures;
   b. Achieved a demonstrated success rate of 95 percent or
greater for percutaneous cardiac intervention procedures;
   c. Experienced a complication rate of less than 5 percent
for percutaneous cardiac intervention procedures; and
   d. Performed diverse cardiac procedures, including, but
not limited to, balloon angioplasty and stenting, rotational
atherectomy, cutting balloon atheroma remodeling, and procedures
relating to left ventricular support capability.

Section 3. Paragraph (k) is added to subsection (3) of
section 408.05, Florida Statutes, to read:

408.05 Florida Center for Health Information and
Transparency.—
(3) HEALTH INFORMATION TRANSPARENCY.—In order to
disseminate and facilitate the availability of comparable and
uniform health information, the agency shall perform the following functions:

(k) Contract with the Society of Thoracic Surgeons to obtain data submitted pursuant to s. 395.1055(9)(d) for publication on the agency's website in a manner that will allow consumers to be informed of aggregate data and to compare pediatric cardiac catheterization programs.

Section 4. This act shall take effect July 1, 2017.